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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,858

06/14/2005

Girij Pal Singh

11336.1001USWO

5757

52835

7590

04/04/2008

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

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EXAMINER

DAVIS, ZINNA NORTINGTON

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,858	<b>Applicant(s)</b> SINGH ET AL.	
	<b>Examiner</b> Zinna Northington Davis	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/05</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

1. Claims 1-29 are pending.
2. The Preliminary Amendment filed June 14, 2005 has been entered.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claims 1-4, a period is needed at the end of the claim. Correction is appreciated.

B. At claim 5, what degree of purity is "substantially free of impurities?"

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteve Quimica, S.A., (Reference B2, cited by Applicants) in view of U.S. Department of Health and Human Services (Reference U, cited by the examiner).

Reference B2, cited by Applicants, teaches a process for obtaining quinapril hydrochloride and solvates. See the entire document. Quinapril is an antihypertensive agent which acts as an angiotensin converting enzyme inhibitor. At page 5, lines 9-16, the prior art teaches that a solvate of quinapril is treated

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with a class 3 solvent to form the corresponding solvate. The difference between the prior art invention is the solvate, methyl acetate or propyl acetate, versus nitroalkane, which is used.

Reference U, cited by the examiner, is largely cumulative of the reference cited in the specification, International Conference of Harmonisation (ICH).

Reference U teaches a list of solvents used in the industry and the guidance for usage. At page 6, Class 2 solvents are used in pharmaceutical products because of their inherent toxicity. At page 7, Class 3 solvents are regarded as less toxic and of lower risk to human health hazard.

It would have been obvious to one of ordinary skill in the art to replace the class 3 solvent of the prior art with a class 2 solvent as instantly claimed. Based upon the teaching of the Class 2 solvent in a pharmaceutical product such as quinapril, there is motivation to interchange one class of solvent for another in view of the similar process for preparation. Accordingly, the claims are unpatentable therefrom.

7. The Information Disclosure Statement filed June 14, 2005 has been considered.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
9. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/  
**Zinna Northington Davis**  
**Primary Examiner**  
**Art Unit 1625**

Znd  
03.21. 2008